II. REMARKS

Applicant gratefully acknowledges the Examiner's determination that claims 38, 39, 42-45, 48 and 49 have been allowed (Office Action, dated November 26, 2009, at 17, lines 15-16; and Office Action, dated June 9, 2009, at 18, lines 13-14).

Independent claims 21, 31, 36 and 37 have been amended to recite that "the substance is dispensed into the wearer's mouth solely by dissolving the substance over time in the wearer's saliva" as supported by page 5, lines 1-8, and by page 6, lines 6-17, and page 7, lines 3-7, of Applicant's specification as originally filed.

The present amendment adds no new matter to the above-captioned application.

A. The Invention

The present invention pertains broadly to a method for dispensing a substance into a mouth, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances. In one embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 21. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 31. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 37. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 38. In yet another embodiment of the present invention, a method of dispensing

a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 39. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 44. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 45.

Various other embodiments, in accordance with the present invention, are recited in the dependent claims. All of the embodiments, in accordance with the present invention, provide the advantage of using a "mouth and tongue stud" to dispense a substance into a wearer's mouth. As would be understood by a person of ordinary skill in the art, a "mouth and tongue stud" is a particular kind of jewelry having features allowing it to be disposed in the mouth of a wearer.

B. The Rejection

Claims 21-27, 31, 36, 37, 46 and 47 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Black (U.S. Patent 4,056,951, hereafter the "Black Patent") in view of Kapling, Jr. (U.S. Patent 6,026,659, hereafter the "Kapling Patent") and Lefkowitz (U.S. Patent 4,676,752, hereafter the "Lefkowitz Patent"). Claims 21-27 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Abramowitz (U.S. Patent 3,500,829, hereafter the "Abramowitz Patent") in view of the Kapling Patent and the Lefkowitz Patent. Claim 31 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kapling Patent in view of the Abramowitz Patent. Claims 21-27 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kapling Patent in view of Edwards (U.S. Patent 4,943,274, hereafter the "Edwards Patent") and the Lefkowitz Patent. Claim 31 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kapling Patent in view of the Edwards Patent.

I respectfully traverse the rejections and request reconsideration of the application for the following reasons.

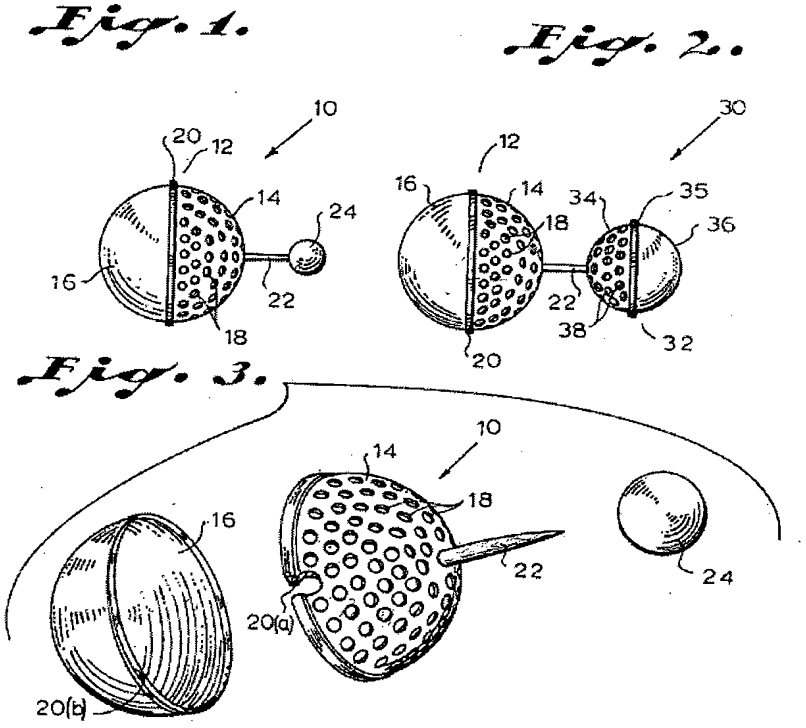
C. Applicant's Arguments

A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation, or other reason, to combine the references to produce the claimed invention. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). A proper rejection under Section 103 also requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants' disclosure. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). An obviousness analysis, however, is a not a rigid formulaic analysis, but is a flexible determination grounded in the facts of the case. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1739 (2007). Indeed, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007).

In the present case, the Examiner has failed to establish a prima facie case of obviousness against the presently claimed invention because the combination of the Black Patent, the Kapling Patent, the Abramowitz Patent, the Lefkowitz Patent, and the Edwards Patent, (i) fails to teach each and every limitation of the claims, (ii) the Examiner has failed to establish any legitimate reason to justify the combination, and (iii) the Examiner has failed to establish that the combination would be enabling and/or that by making the combination a person of ordinary skill in the art would have a reasonable expectation of arriving at the claimed invention.

i. The Black Patent

The Black Patent discloses a "pierced earring having perfuming means" as shown in Figures 1, 2 and 3 reproduced below, and not a mouth and tongue stud. As would be instantly appreciated by a person of ordinary skill in the art, the earring shown in Figures 1, 2 and 3 is not suitable for use in a wearer's mouth because the nut (24) is fastened to a pointed "post" (22). As plainly shown in



Figures 1, 2 and 3, the posts are pointed pins and the nut members merely stick on the ends of the pointed pins. Such an attachment structure is unsuitable for use in a mouth and tongue stud because the attachment is not robust. Furthermore, should the pin detach from the nut while in use, a wearer would have a loose pin in his mouth. Also, the structures disclosed by Black are constructed to release a perfume into the air (See Abstract). Perfumes are worn on the skin and are not ingested. One of ordinary skill in the art would know that perfumes include generally toxic and noxious solvents that should not be put in the mouth.

For all of the above reasons, it is plain that the device disclosed by Black could not be safely used in the oral cavity. Black discloses an earring employed for external use only.

As admitted by the Examiner (Office Action, dated June 8, 2009, at 3, lines 5-10), the Black

Patent does not teach, or suggest, (i) "dispensing the substance into the wearer's mouth" as recited by claims 21, 31, 36 and 37, (ii) "the substance is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by claims 21, 31, 36 and 37, (iii) "mounting the bar of the stud in a fistula formed in a wearer's tongue or in the wearer's lip" as recited by claims 21, 31, 36 and 37, and (iv) "the substance is selected from the group consisting of a breath freshener and a flavoring agent" as recited by claims 21 and 36. The Black Patent also fails to teach, or suggest, (v) "the substance is a medication" as recited by claims 31 and 37, and the Black Patent fails to teach, or suggest, (vi) "providing a mouth and tongue stud including means for dispensing a substance..." as recited in independent claims 21, 31, 36 and 37.

ii. The Kapling Patent

U.S. Patent 6,026,659, the Kapling Patent, discloses "body jewelry device and method of making the same," wherein, as shown in Figure 1, the body jewelry device (10) includes a post (12) with cap (14) coupled to one end of the post (12) and cap (16) coupled to the other end of the post (12), (See Kapling Patent, col. 3, lines 38-42). The Kapling Patent, at col. 3, lines 43-44, discloses that the post (12) is disposed in the pieced passageway in a wearer's tongue.

As admitted by the Examiner (Office Action, dated November 11, 2006, at 3, lines 18-21; Office Action, dated March 24, 2008, at 18-24), the Kapling Patent does not teach, or suggest, "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" as recited by independent claims 21, 31, 36 and 37. As also admitted by the Examiner (Office Action, dated November 26, 2008, at 3, lines 18-24; Office Action, dated March 24, 2008, at 18-24), the Kapling Patent does not teach, or suggest, "dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36 and 37.

iii. The Abramowitz Patent

The Abramowitz Patent discloses an "earhole piercing and treating apparatus" as shown in Figures 1 to 13. In an embodiment shown in Figures 4 and 10, the Abramowitz Patent discloses a device comprising a slotted tube (14) provided with an end ball (16) on one end and a squeeze bulb (44) on the other end, (Abramowitz Patent, col. 3, lines 17-25). For convenience, Figures 4 and 10 of the Abramowitz Patent are reproduced below. The Abramowitz Patent discloses that a medicament or perfume may be placed in the bulb (44) so that when the bulb is squeezed, the medicament is forced out of the bulb and out of the elongated slot (32) of the tube (14), (Abramowitz Patent, col. 3, lines 17-25).

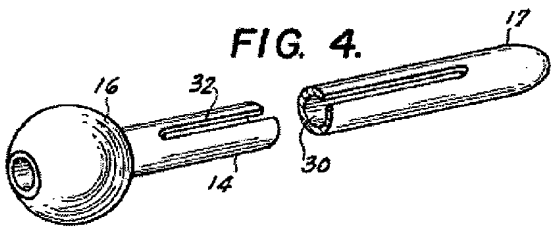


FIG. 4.

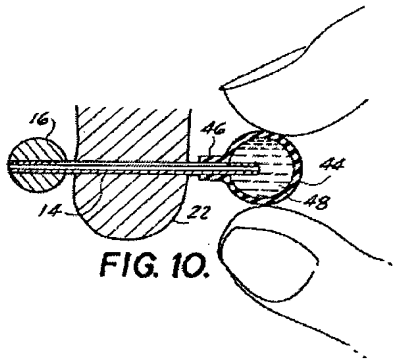


FIG. 10.

A person of ordinary skill in the art would immediately recognize that the device shown in Figure 10 of the Abramowitz Patent is a "syringe." As defined by THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1306 (1979), of record, a "syringe" is "a device used to inject fluids into the body or draw them from it." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, at 1306, shows a picture of a syringe that employs a plunger to inject fluids through a needle, as would be immediately recognized by a person of ordinary skill in the art. The device shown in Figure 10 of Abramowitz employs a rubber "squeeze bulb" (44) in place of the plunger to inject fluids when the bulb is squeezed (See Abramowitz Patent, col. 3, lines 17-25). A person of ordinary skill in the art would instantly recognize that the "squeeze bulb" of Figure 10 of the Abramowitz Patent is a type of syringe known as a "bulb syringe."

Of note, claim 3 of the Abramowitz Patent recites "medicament injecting means comprising a

squeezable-ball containing a medicament...whereby upon squeezing the ball the medicament is ejected...." A person of ordinary skill in the art would instantly realize that the Abramowitz Patent is describing the ball (44) as an "injecting means," which is exactly what a syringe is.

In view of the above, it is clear that the Abramowitz Patent does not teach, or suggest, (i) "providing a mouth and tongue stud including means for dispensing a substance..." as recited in independent claims 21, 31, 36 and 37 of the present application because the Abramowitz Patent discloses various devices, each including a syringe, that is mounted into an earlobe. Furthermore, the Abramowitz Patent does not teach, or suggest, (ii) "the substance is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing into the wearer's mouth" as recited by claims 21 and 31, and (iii) "the substance is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by claims 36 and 37. On the contrary, the Abramowitz Patent discloses that an "injection means" (i.e., a bulb syringe) is required to eject a substance (i.e., medicament or perfume) from Abramowitz's device. Furthermore, **the Examiner has conceded that the Abramowitz Patent does not teach, or suggest, "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, and 37** (Office Action, dated June 8, 2009, at 24, line 20, to 25, line 4).

Another deficiency of the Abramowitz disclosure is that the tube (14) is hollow as shown in Figures 4 and 10. Therefore, the Abramowitz Patent cannot teach, or suggest, (iv)

> "the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member,"

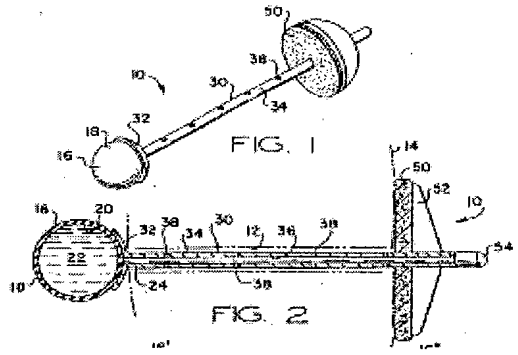
as recited by independent claims 36 and 37. In fact, the device disclosed by the Abramowitz Patent employs a hollow tube (14) and would be inoperable if it employed a "solid bar that is without an internal cavity" as recited by claims 36 and 37.

The Device Disclosed by Abramowitz is for External Use Only

The Abramowitz Patent describes an "an earlobe piecing and treating apparatus" that is placed in the piercing of an earlobe (22), (Abramowitz Patent, col. 2, lines 38-40, and Figure 10). The Abramowitz Patent does not teach, or suggest, that this device is suitable for use in the oral cavity of a wearer. On the contrary, because the apparatus disclosed by Abramowitz employs either a friction grip fastener (18) or a rubber-like squeeze bulb placed on the free end of tube (14), (Abramowitz Patent, col. 2, lines 28-37, and col. 3, lines 17-25), it is not suitable for use in the mouth of a wearer as would be instantly realized by a person of ordinary skill in the art.

iv. The Edwards Patent

The Edwards Patent discloses an "apparatus for applying earlobe medicine" which is inserted into the earlobe (See Abstract). This ear apparatus is not a mouth and tongue stud and there is no teaching, or suggestion, that the apparatus would be used in the oral cavity. One skilled in the art would recognize that the apparatus (10) as shown in Figures 1 and 2 does not have the features of a mouth and tongue stud and is not suitable for use in the mouth. For convenience, Figures 1 and 2 of the Edwards Patent are reproduced below because they illustrate the many deficiencies of the apparatus (10) disclosed by Edwards.



In particular, apparatus (10) has a relatively pointed protruding "end" (54). Mouth and tongue studs do not have points such as "end" (54) because such a pointed structure would seriously damage the mucosal surfaces in the mouth. Apparatus (10) disclosed by the Edwards Patent also has a felt pad (50) as a backing for retainer (52). Mouth and tongue studs, unlike earrings and devices for

inserting into the earlobe, are restricted to certain non-toxic suitable materials for putting into the mouth. Felt is not a suitable material for the mouth. In the wet environment of the mouth, the felt would quickly degrade, break apart, and present an aspiration hazard. Furthermore, retainer (52) as shown in Figure 2 is only held in place by friction. Mouth and tongue studs cannot use simple friction retainers because the connection between the retainer and the rest of the apparatus is not robust. The mouth is a very active place with eating, drinking, speaking, and facial expressions going on. As a result, mouth and tongue studs must be securely inserted into the tongue or lip. As is commonly known by those skilled in the art, if a mouth and tongue stud falls out of its piercing and into the mouth there is a serious potential for harm from aspirating the stud or its component parts into the lungs or from choking. Generally, a threaded connection, or a weld and the like, is used to attach an "end member" of the mouth and tongue stud to the bar because this is a suitably secure connection. Friction retainers or clasps are not used.

Apparatus (10) disclosed by Edwards also has a resilient housing (16) made of neoprene, polypropylene or polyethylene so that housing (16) is squeezable (Edwards Patent, col. 2, lines 15-25, and col. 3, lines 3-10). Such a squeezable housing is unsuitable for use as a structure of a mouth and tongue stud for several reasons. First, housing (16), being compressible, would defeat one of the purposes of a mouth and tongue stud, being to enhance sexual activity. Second, the housing (16) could not hold the "antibiotic gel, petroleum or aloe-based ointments" (Edwards Patent, col. 2, lines 22-24) effectively because, once the apparatus (10) was inside the mouth, the housing would be compressed by some portion of the mouth. Thus, once in the mouth, housing (16) would not be an effective reservoir.

Furthermore, a person of ordinary skill in the art would immediately realize that the apparatus (10) disclosed by the Edwards Patent is a syringe. Specifically, apparatus (10) includes a tubular conduit (30), i.e., a needle, and a squeezable resilient housing or reservoir (16), wherein the apparatus (10) is operated to force pressurized medicament (22) through the conduit (30) and into an ear piercing when the reservoir (16) is squeezed (Edwards Patent, col. 3, lines 3-10). More

specifically, a person of ordinary skill in the art would immediately realize that apparatus (10) is a "bulb" syringe wherein the reservoir (16) is the bulb. Thus, a person of ordinary skill in the art would instantly realize that the Edwards Patent does not teach, or even suggest, (i) "providing a mouth and tongue stud...," (ii) "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, and 37, and (iii)

> "the substance is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing into the wearer's mouth,"

as recited by claims 21 and 31. Instead, Edwards discloses a syringe mounted to an earlobe.

Given the fact that the apparatus (10) disclosed by Edwards has a different structure from the present invention, is not a mouth and tongue stud, cannot function as a mouth and tongue stud, and has no parts that would be suitable for use by a mouth and tongue stud, any rejection under 35 U.S.C. §§ 102(b) and 103(a) relying upon the Edwards reference is untenable. For all of the above reasons, a person of ordinary skill in the art would realize that apparatus (10) is a syringe that is inserted into an earlobe piercing (i.e., a skin piercing), and that it would be contrary to the common sense of a person of ordinary skill in the art to employ the apparatus (10) in the mouth of a wearer.

As conceded by the Examiner (Office Action, dated August 3, 2007, at 4, lines 14-16), the Edwards Patent does not teach, or suggest, "the substance comprises a breath freshener" as recited by claim 22 and "the substance comprises a flavoring agent" as recited by claim 23. **The Examiner also concedes that the Edwards Patent does not teach, or suggest, "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, and 37** (Office Action, dated June 8, 2009, at 24, line 20, to 25, line 4).

The Edwards Patent also does not teach, or suggest, a bar that is "a straight solid bar that is without an internal cavity" as recited by independent claims 36 and 37. Specifically, the Edwards Patent discloses a tubular conduit (30) that is clearly hollow as shown in Figure 3. Therefore, the

Edwards Patent cannot teach, or suggest, (iv)

> "the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member,"

as recited by independent claims 36 and 37. In fact, the device disclosed by the Edwards Patent employs a hollow tube (30) and would be inoperable if it employed a "solid bar that is without an internal cavity" as recited by claims 36 and 37.

The Device Disclosed by Edwards is for External Use Only

The Edwards Patent describes an "an apparatus for applying earlobe medication" that is placed in the piercing of an earlobe, (Edwards Patent, col. 1, lines 38-40). The Edwards Patent does not teach, or suggest, that this device is suitable for use in the oral cavity of a wearer.

v. The Lefkowitz Patent

The Lefkowitz Patent discloses a "gingival breath deodorizer and bite guard" as shown in Figure 1, which is reproduced below for convenience. The body (10) of the device includes a bladder vesicle (24) of a "flexible duckbill construction" with a filing aperture (28) at one end and a dispensing valve (26) at the other end (Lefkowitz Patent, col. 4, lines 37-51). When bladder (24) is pressed, a "breath deodorizing liquid" is discharged from the valve (26), (Lefkowitz Patent, col. 4, lines 46-51).

A person of ordinary skill in the art would immediately realize that the "gingival breath deodorizer and bite guard" device disclosed by the Lefkowitz Patent is just another syringe. The Lefkowitz Patent does not teach, or suggest, (i) "providing a mouth and tongue stud...," and (ii) "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the

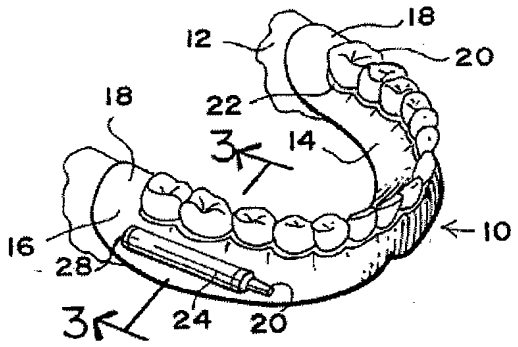


Figure 1 of Lefkowitz Patent

wearer's saliva" as recited by independent claims 21, 31, 36, and 37, (iii) "a straight solid bar that is without an internal cavity" as recited by independent claims 36 and 37. **The Examiner concedes that the Lefkowitz Patent does not teach, or suggest, "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, and 37** (Office Action, dated June 8, 2009, at 24, line 20, to 25, line 4).

vi. Summary of the Disclosures

The Kapling Patent discloses a conventional bar bell stud that is inserted through a passageway in a user's tongue. The Kapling Patent does not teach, or suggest, any "means for dispensing a substance" and/or any related features.

The Black Patent discloses an earring for dispensing perfume. The Black Patent does not teach, or suggest, a "mouth and tongue stud including a means for dispensing a substance" as claimed, or even a device suitable for use in a wearer's mouth.

The Abramowitz Patent discloses an earhole piercing and treating apparatus that is inserted into the piercing of an earlobe. The device disclosed by Abramowitz is a syringe and it is not suitable for use in a wearer's mouth.

The Edwards Patent discloses an apparatus for applying earlobe medicine that is inserted into the piercing of an earlobe. The device disclosed by Edwards is another syringe and it is also not

suitable for use in a wearer's mouth.

The Lefkowitz Patent discloses a gingival breath deodorizer and bite guard that is used in a wearer's mouth. The device disclosed by the Lefkowitz Patent includes yet another syringe.

The combination of the disclosures of the Kapling Patent, the Black Patent, the Abramowitz Patent, the Edwards Patent, and the Lefkowitz Patent does not teach, or even suggest, (i) "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" and (ii) "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36 and 37, and (iii)

> "the substance is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing into the wearer's mouth,"

as recited by claims 21 and 31, and (iv)

> "the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member,"

as recited by independent claims 36 and 37. In fact, **the Examiner concedes that none of the disclosures of the Kapling Patent, the Black Patent, the Abramowitz Patent, the Edwards Patent, and the Lefkowitz Patent teaches, or suggests, "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, and 37** (Office Action, dated June 8, 2009, at 24, line 20, to 25, line 4).

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against any claim of the above-captioned application.

vii. Dispensing a Substance Using Saliva is Not Taught by Kapling, Black, Abramowitz, Edwards or Lefkowitz

As repeatedly admitted by the Examiner (Office Action, dated June 8, 2009, at 24, line 20, to 25, line 4; Office Action, dated November 26, 2008, at 5, lines 5-8, and at 12, lines 11-14; Office

Action, dated March 24, 2008, at 6, lines 5-7, and at 11, lines 8-9), the combination of the Kapling Patent, the Black Patent, the Abramowitz Patent, the Edwards Patent, and the Lefkowitz Patent fails to teach, or suggest, "the substance...is dispensed into the wearer's mouth...by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, and 37. Instead, the Examiner **speculates** that (a) some of the substance remaining in the syringe needles (i.e., Abramowitz's slotted tube (14) or Edwards' tubular conduit (30)) would subsequently be dissolved by wearer's saliva backflowing into the needle due to a vacuum created following injection of substance into the mouth, and that this backflow saliva with dissolved substance either spontaneously flows from the needle, or is subsequently injected from the needle, into the wearer's mouth (Office Action, dated June 8, 2009, at 24, lines 5-19; Office Action, dated November 26, 2008, at 5, lines 8-18; at 9, line 12, to 10, line 2; and at 19, lines 12-17). The Examiner's theories are untenable as a matter of law, and fail to support a prima facie case of obviousness, for the following reasons.

a. The Obviousness Rejections are Untenable Because They are Based on an Impermissible View of Inherency

First and foremost, **the Federal Circuit has ruled that speculation regarding how a device resulting from a combination of prior art disclosures might operate cannot establish a prima facie case of obviousness because obviousness cannot be predicated on the unknown**. In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989). In Newell, 13 U.S.P.Q.2d at 1250, the Federal Circuit flatly rejected the Patent Office's contention that a data cartridge having a belt-to-capstan drive system resulting from the combined disclosures of multiple patents would have been obvious because the hybrid device would have a belt drive that inherently provides greater surface contact and inherently provides better power transfer. Specifically, the Von Behren Patent and an earlier Newell Patent disclosed data cartridges with capstan-to-capstan drive systems, and the Weiss Patent disclosed a belt-to-roller drive system wherein motive power was transferred directly from the feeding belt to the tape. In re Newell, 13 U.S.P.Q.2d at 1249-50. The Federal Circuit held that the

indirect power transfer from the power belt through the capstan to the drive belt, as claimed, could not be inferred from the combination of patents because none of the patents disclosed this operational feature, and because such a "retrospective view of inherency" cannot establish a prima facie case of obviousness. In re Newell, 13 U.S.P.Q.2d at 1250.

The Federal Circuit's holding in Newell is on point with the facts of this case. As admitted by the Examiner (Office Action, dated June 8, 2009, at 24, line 20, to 25, line 4), neither the Kapling Patent, the Black Patent, the Abramowitz Patent, the Edwards Patent, nor the Lefkowitz Patent, either alone or in combination, teaches or suggests using the wearer's saliva to dispense a substance by dissolving it in the wearer's saliva. Therefore, Applicant's invention is novel.

The Examiner erroneously contends that

> "the test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. Edwards and Abramowitz fails to disclose that the use of saliva (sic) since these references are directed to external use where saliva is not present. However, Kapling teaches that use of earrings in other body member such as the mouth is well known in piercing art. A person of ordinary skill in the art will acknowledge that the saliva is capable of flowing through any surface provided in the mouth. Therefore, the saliva will flow through any surface of the stud disclosed by Edwards of (sic) Abramowitz since these studs do not provide any closing structure that will prevent the movement of saliva through the stud."

(Office Action, dated June 8, 2009, at 25, lines 4-13).

The Examiner's contention that a hybrid device resulting from a combination of two or more of the Kapling, Black, Abramowitz, Edwards and Lefkowitz disclosures would operate to dispense a substance from the hybrid device into a wearer's mouth by dissolving the substance in the wearer's saliva amounts to a "retrospective view of inherency" because, as admitted by the Examiner, the limitation does not come from any one of the Kapling, Black, Abramowitz, Edwards and Lefkowitz disclosures. Instead, the Examiner necessarily speculates regarding how the hybrid device resulting from the combination of disclosures might operate if placed in a wearer's mouth. Such speculation is impermissible in view of the Federal Circuit's ruling in In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989).

The Examiner's improper speculation is also based on unsubstantiated "Official Notices."

Specifically, the Examiner contends that "[a] person of ordinary skill in the art will acknowledge that the saliva is capable of flowing through any surface provided in the mouth" (Office Action, dated June 8, 2009, at 25, lines 9-10). **The Examiner's contention amounts to an unsubstantiated Official Notice**. On the contrary, persons of ordinary skill in the art would understand that saliva is a viscoelastic, non-Newtonian fluid that consists of water, glycoproteins, enzymes, antimicrobial substances and electrolytes (See Abstract of A. Preetha et al., *Comparison of Artificial Saliva Substitutes*, 18 TRENDS BIOMATER. ARTIF. ORGANS 178-186 (2005), a copy of which is filed herewith as "Exhibit AA"), and that it tends to clog small tubes (See, e.g., Webpage downloaded October 6, 2009 from http://books.google.com/, pertaining to a preview of "Human saliva: clinical chemistry and microbiology, Volume 1," by Jorma O Tenovuo, page 17, a copy of which is filed herewith as "Exhibit AB" and which states that "Gel permeation chromatography is especially affected by the viscosity of the sample; salivary mucins tend to clog columns"). Therefore, a person of ordinary skill in the art would not believe or "acknowledge" that saliva is capable of flowing through any surface provided in the mouth as the Examiner contends.

In view of the above factual evidence rebutting the Examiner's alleged Official Notice, the Examiner must now produce substantial evidence to support the "Official Notice" or withdraw it and the conclusions the Examiner asserts are based on the "Official Notice." See, e.g., In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001).

For all of the above reasons, the Examiner's obviousness rejection is untenable and must be withdrawn because it violates the Federal Circuit's rule against retrospective views regarding how hybrid devices might inherently operate, and because it is based on unsubstantiated, and false assertions of fact alleged by Official Notice.

b. Obviousness Determinations Must be Based on Substantial Evidence and not on Speculation

A prima facie case of obviousness must be based on substantial evidence and not on what the

Examiner contends is "common sense." In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). In this case, the Examiner contends that "obviously" saliva will travel from a wearer's mouth and into the needles disclosed by the Abramowitz Patent and the Edwards Patent, and then the saliva will dissolve some of the substance in the needles and then flow back out again based on the Examiner's speculative "vacuum" theory (See Office Action, dated November 26, 2008, at 5, lines 8-18; and at 12, line 14, to 13, line 2). The Examiner's contention is flawed because saliva is a viscoelastic, non-Newtonian fluid as evident from Exhibit AA filed herewith, which tends to clog small tubes as evident from Exhibit AB, and there is no evidence of record that would teach, or suggest, that the slotted tube (14) of Abramowitz, and/or the tubular conduit (30) of Edwards, are dimensioned so that saliva, or any other bodily fluid, should spontaneously flow up into these needles.

Even assuming that such a saliva backflow would occur due to a vacuum in the needle (which is a wholly invalid assumption), both the Abramowitz Patent and the Edwards Patent disclose using a squeezable bulb to eject medicament. As would be instantly understood by a person of ordinary skill in the art, once the bulb (44) of Abramowitz, or bulb (16) of Edwards, has been squeezed to eject medicament there will be a negative pressure in the bulb. This negative pressure, if sufficient to draw saliva into the tubes (14) or (30) in the first place as the Examiner contends, would subsequently prevent saliva from exiting the tubes (14), (30) once saliva has been sucked in.

In other words, even assuming *arguendo* viscoelastic saliva was sucked up into the tubes (14) or (30), as the Examiner contends (which is an invalid assumption), it would be trapped in the tubes (14), (30) by (i) the negative pressure generated by the bulb (44) or (16), respectively, and (ii) by the fact that saliva is viscous and sticky so it will get stuck in the needle as supported by Exhibits AA and AB, and (iii) the saliva will remain stuck in the needle due to the capillary effect. Consequently, even if saliva were drawn into the tubes (14) or (30), a person of ordinary skill in the art would instantly realize that it would form a saliva plug trapping the substance within the tubes (14) or (30) instead of "dispensing" the substance dissolved in saliva by flowing back out of the tubes (14) or (30) as the Examiner contends.

The Examiner's second theory, wherein substance dissolved in backflowed saliva is "dispensed" when it is injected back into the wearer's mouth when the bulbs (44) or (16) are squeezed again (Office Action, dated November 26, 2008, at 19, lines 12-17), does not reasonably read on the limitation

> "the substance is dispensed into the wearer's mouth solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing into the wearer's mouth,"

as recited by claims 21 and 31. Specifically, the Examiner's second injection theory requires that the backwashed saliva containing dissolved substance be subsequently injected into the wearer's mouth because it is trapped in the needle. Because saliva trapped in the needled is not free to flow from the needle into the wearer's mouth, then the dissolved substance is also not free to flow from the needle into the wearer's mouth solely due to dissolving the substance in saliva. Therefore, the hybrid device resulting from the combination of the Kapling, Abramowitz, Edwards and Lefkowitz disclosures cannot dispense the substance

> "into the wearer's mouth solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing into the wearer's mouth,"

as recited by claims 21 and 31. Likewise, the hybrid device resulting from the combination of the Kapling, Abramowitz, Edwards and Lefkowitz disclosures cannot dispense the substance

> "into the wearer's mouth solely by dissolving the substance over time in the wearer's saliva,"

as recited by claims 36 and 37.

In other words, because the dissolved substance will be trapped in the needle of the Examiner's hybrid device, as recognized by the Examiner (Office Action, dated November 26, 2008, at 19, lines 12-17), it is not "free to flow from the means for dispensing into the wearer's mouth" as recited by claims 21 and 31because it has to be pushed out by the injection means (i.e., squeeze bulb). Furthermore, because the Abramowitz Patent, the Edwards Patent, and the Lefkowitz Patent each disclose a device that employs a syringe to dispense a substance, the combination of these devices with the stud disclosed by Kapling results in a syringe, which cannot meet the limitation wherein "the

substance is dispensed into the wearer's mouth **solely** by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36 and 37 because the syringe employs injection, at least in part, to dispense the substance.

While the Examiner is encouraged to give Applicant's claims the broadest reasonable interpretation consistent with the specification, In re Hyatt, 54 U.S.P.Q.2d 1664, 1667 (Fed. Cir. 2000), **the Examiner is not free to give an unreasonable interpretation to the claimed invention**. In this case, the Examiner has not given a reasonable interpretation to the invention as claimed because injection of substance, whether injected directly from the bulb (44), (16), or injected substance dissolved in backwashed saliva, does not read on

> "the substance is dispensed into the wearer's mouth solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing into the wearer's mouth,"

as recited by claims 21 and 31 because substance that has to wait until the bulb is squeezed to effect an injection of substance, or an injection of substance dissolved in backwashed saliva, is not "free to flow from the means for dispensing into the wearer's mouth." Furthermore, **the substance, which is dispensed solely by, or at least in part by, injection is not dispensed "solely by dissolving the substance over time in the wearer's saliva" as supported by claims 21, 31, 36 and 37**.

In sum, the Examiner concedes that the hypothetical device injects medication from the device into the piercing without using saliva. The Examiner erroneously and impermissibly speculates that perhaps some saliva will travel into the needle of the syringe due to a vacuum, dissolve some trace amount of substance remaining in the syringe needle, and then flow back out again either spontaneously (which is highly unlikely) or manually when injected. Assuming *arguendo* that the Examiner's speculative theory is correct (which is an invalid assumption), it still does not teach, or suggest, that

> "the substance is dispensed into the wearer's mouth solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing into the wearer's mouth,"

as recited by claims 21 and 31 because the substance is not free to flow into the wearer's mouth

because it is trapped in the bulb or the needle until it is expelled by injection. Likewise, the Examiner's combination of Kapling, Abramowitz, Edwards and Lefkowitz does not teach, or suggest, "the substance is dispensed into the wearer's mouth **solely** by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36 and 37.

For all of the above reasons, the Examiner's contention that the hypothetical device "obviously" operates so that "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" is untenable and must be withdrawn because the Examiner's theory is factually incorrect, and because the theory relies on an impermissible retroactive view of inherency.

viii. No Legitimate Reason to Justify the Combination of Patents

The Examiner has failed to establish a proper teaching, motivation, suggestion, or any legitimate reason, to combine the Kapling Patent, the Abramowitz Patent, the Black Patent, the Edwards Patents, and the Lefkowitz Patent to arrive at the claimed invention. See KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Rouffet, 47 U.S.P.Q.2d 1453, 1456 (Fed. Cir. 1998). In particular, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007). In this case, the Examiner has failed to establish a proper teaching, suggestion, motivation, or any legitimate reason, to justify the combination of the Kapling Patent, the Black Patent, the Abramowitz Patent, the Edwards Patents, and the Lefkowitz Patent because the combination falls short of the claimed invention for all of the reasons discussed above. Furthermore, the Examiner has failed to adduce any legitimate reason to justify the combination for the following reasons.

The Kapling Patent discloses a conventional bar bell stud for inserting into a tongue piercing, and the conventional bar bell stud does not include any means for dispensing a substance. The Black Patent discloses an earring that dispenses perfume, and is suitable only for external use. The

Abramowitz Patent discloses an earhole piercing and treating apparatus that is inserted into the piercing of an earlobe, and this apparatus is a syringe and is suitable for external use only. The Abramowitz Patent discloses that its "injection means" structure is used to eject medicament into an ear piercing in order to treat sore, infected ear piercings, (Abramowitz Patent, col. 1, lines 43-48; col. 2, lines 11-14; col. 3, lines 17-25, and Figure 10), and is suitable only for external use. The Edwards Patent discloses an apparatus for applying earlobe medicine that involves another syringe design, which is also only suitable for external use. The Edwards Patent discloses using a squeezable reservoir (16) and attached tubular conduit (30) to inject medicament into the piercing of an earlobe by squeezing the reservoir (16) in order to avoid frequent infection of the earlobe piecing (Edwards Patent, col. 1, lines 28-35; and col. 3, lines 2-12).

a. The Combination of Black, Kapling and Lefkowitz

The Examiner contends that it would have been obvious to a person of ordinary skill in the art, at the time the present invention was made, to have modified the earring disclosed by the Black Patent so that it includes structures according to Kapling and to use it in the mouth of a wearer to dispense a breath freshener, flavoring agent and/or medication based on the disclosure of Lefkowitz (Office Action, dated June 8, 2009, at 3, line 3, to 5, line 8). The Examiner's contention is flawed because the Examiner has not demonstrated any legitimate reason for making the proposed combination and because the common sense of those skilled in the art would demonstrate why the proposed combination is not obvious. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007).

Specifically, Black discloses an earring for dispensing perfume, which is inherently dispensed by evaporation or diffusion into the air. Operation of the device disclosed by Black occurs spontaneously without reliance upon secretions supplied by the wearer. Furthermore, Black's device is designed for external use only as would be instantly appreciated by those of ordinary skill in the art. The Kapling stud is for use on the skin or in the tongue. However, the combination of Black and

Kapling would result in a device for dispensing perfume into the air, which would necessarily be a device for external use only. The Lefkowitz device discloses dispensing breath fresheners and other substances into the wearer's mouth using a syringe built into a bite guard. A person of ordinary skill in the art would have to use imagination to construct a hybrid device based on Black, Kapling and Lefkowitz because the device resulting from the combination of Black and Kapling pertains to dispensing perfuming agents into the air by diffusion whereas Lefkowitz pertains to injecting liquid substances in the mouth. In other words, a person of ordinary skill in the art has no legitimate reason to employ the device disclosed by Black and Kapling to dispense a liquid substance in the mouth of a wearer because the combination of Black and Kapling would result in a device for external use for dispensing perfume in the air, and Lefkowitz discloses dispensing liquids into the mouth by injection.

With respect to combinations relying on the Abramowitz Patent and/or the Edwards Patent, the Examiner contends that

> "[t]he mouth is prone to infections just like any other part of the body. Body members being pierced are susceptible to infections especially when the body members have been recently pierced. The use of earrings to dispense medication into the body members that are pierced in order to prevent or fight infections is well known in the art as disclosed by Abramowitz and Edwards...a person of ordinary skill in the art will acknowledge that combining the elements of Abramowitz, Kapling and Lefkowitz or Edwards, Kapling and Lefkowitz will yield the predictable results of providing a device that will prevent or fight infections in the wearer's mouth by using the studs that will dispense the medication into the wearer's mouth."
> (Office Action, dated June 8, 2009, at 19, line 14, to 20, line 3).

The Examiner's conclusions pertaining to prevention or fighting infections in a wearer's mouth by using studs are erroneous as demonstrated by the following evidence.

Filed herewith labeled as "Exhibit AC" is a copy of "Declaration under 37 C.F.R. § 1.132," executed by Wesley Scott Ashton, M.D. on June 17, 2003 (hereafter, the "Ashton Declaration"), and previously filed in U.S. Patent Application No. 09/881,806, which is the parent application to the present case. Exhibit AC includes Appendix A and Appendix B. Appendix C referred to by the Ashton Declaration pertains to documents relied upon in support of the Declaration. Because these documents are already of record in view of the Information Disclosure Statement (IDS) filed August 5, 2004, Appendix C has not been included with Exhibit AC.

The Ashton Declaration includes a discussion of relevant medical articles and references pertaining to infections of tongue piercings and skin piercings (Ashton Declaration, Sections 4 to 7). As summarized in Table 1 of the Ashton Declaration, skin infection associated with skin piercing is the most common complication of a skin piercing, whereas local infection associated with a mouth or tongue piercing is rare. Furthermore, Table 1 of the Ashton Declaration confirms that application of a topical antibiotic to an infected skin piercing is a medically accepted treatment, such as is disclosed by the Abramowitz Patent and the Edwards Patent. However, the medically accepted treatment of an infected tongue related to piercing is removal of the tongue piercing according to C.S. Perkins et al., *A Complication of Tongue Piercing*, 182 BR. DENT. J. 147-148 (1997), of record, because of the risk of airway compromise from an infected, swollen tongue (See Ashton Declaration, at 7, line 10, to 8, line 6, and at 14, lines 8-20, and Table 1).

In view of the above facts, the Examiner's contention that

> "combining the elements of Abramowitz, Kapling and Lefkowitz or Edwards, Kapling and Lefkowitz will yield the predictable results of providing a device that will prevent or fight infections in the wearer's mouth by using the studs that will dispense the medication into the wearer's mouth,"
> (Office Action, dated June 8, 2009, at 19, line 21, to 20, line 3)

is an incorrect statement of fact. The evidence of record establishes that a modified "stud" would not be used to treat an infected tongue piercing because medical common sense dictates that the stud should be removed and the patient placed on systemic antibiotics, whether oral or by injection. Therefore, **the Examiner has established no legitimate reason for combining Abramowitz, Edwards, Lefkowitz and Kapling because the resulting device would not be used to treat an infected tongue piercing**.

With respect to the issue of preventing tongue piercing infections, review of the medical literature in 2002 demonstrates that tongue piercing infections are exceptionally rare (Ashton Declaration, at 15, lines 9, to 16, line 2, at 19, line 1, to 20, line 4, and Table 1). Furthermore, the medically accepted therapy for preventing tongue piercing infection would involve a soft diet, good oral hygiene to include washing out the mouth with water or an anti-septic mouthwash after meals,

and optionally a peroxide rinse twice a day to decrease the bacterial load in the mouth (Ashton Declaration, at 11, lines 5-12, at 12, lines 9-15, and at 16, lines 8-12). The volume of peroxide required to perform an adequate peroxide rinse would exceed the volume of fluid that could be reasonably dispensed by a tongue stud (Ashton Declaration, at 16, lines 18-22). Therefore, the evidence of record establishes that a modified "stud" would not be used to prevent an infected tongue piercing because medical common sense dictates that infection prevention involves a soft diet, rinsing the mouth out after meals, and optionally peroxide rinses. None of these preventive therapies may be effectively administered using a modified tongue stud. Therefore, **the Examiner has established no legitimate reason for combining Abramowitz, Edwards, Lefkowitz and Kapling because the resulting device would not be used to administer therapy to prevent an infected tongue piercing**.

The evidence based medical conclusions provided by the Ashton Declaration are supported directly by the medical literature of record, which establish that (i) infections of mouth piercings are rare, and (ii) the treatment of mouth piercing infections does not involve the use of medicaments dispensed by a syringe into the piercing.

As disclosed by the Edwards Patent, infection of earlobe infections are frequent (Edwards Patent, col. 1, lines 28-31). This fact is further supported by Barton Schmidt, *Your Child's Health: The Parent's Guide to Symptoms, Emergencies, Common Illnesses, Behavior and School Problems*, 524-527 (Bantam Books 1991), of record. On the other hand, mouth infections following mouth trauma are rare (See, e.g., Barton Schmidt, *Your Child's Health: The Parent's Guide to Symptoms, Emergencies, Common Illnesses, Behavior and School Problems*, 77-78 (Bantam Books 1991), of record). A person of ordinary skill in the art would know that pierced earlobes have a relatively high rate of infection, whereas mouth piercings do not, and that this difference in infection rates is due to the fact that the earlobe is a poorly vascularized structure that is colonized with aerobic gram positive bacteria, whereas mouth structures are highly vascularized and are colonized mainly with anaerobic bacteria. A person of ordinary skill in the art would also know that ear piercings may be treated by

applying rubbing alcohol to the post of an earring (See, e.g., Barton Schmidt, *Your Child's Health: The Parent's Guide to Symptoms, Emergencies, Common Illnesses, Behavior and School Problems*, 526 (Bantam Books 1991), of record). On the other hand, a person of ordinary skill in the art would know that treatment of mouth trauma involves use of anti-septic mouthwash (See, e.g., M. Chen et al., *Tongue Piercing: a New Fad in Body Art*, 172 BR. DENT. J. 87 (1992), of record), which a person of ordinary skill in the art would also know is used in amounts of about 30 cc to 60 cc as a rinse (Ashton Declaration, at 11, lines 11-12, and at 16, lines 18-20). A person of ordinary skill in the art would also know that a truly infected tongue piercing is likely to be complicated by tongue swelling and airway compromise so that treatment would require removal of any tongue jewelry (See, e.g., C.S. Perkins et al., *A Complication of Tongue Piercing*, 182 BR. DENT. J. 147-148 (1997), of record, hereafter the "Perkins Article").

In sum, a person of ordinary skill in the art would know that while infected earlobe piercings are common and are generally caused by gram positive aerobic bacteria, infected piercings of the mouth are rare and are generally caused by normal oral flora (i.e., anaerobic bacteria), (See Ashton Declaration, Table 1). Furthermore, a person of ordinary skill in the art would know that while infected earlobe piercings may be treated with topical anti-septics and antibiotics while maintaining the earring post in the piercing, infected mouth piercings would be treated with voluminous mouthwashes, systemic antibiotics (oral or parenteral) and removal of any jewelry (See Ashton Declaration, Table 1). In view of these facts, a person of ordinary skill in the art would have no legitimate reason to modify the device disclosed by the Kapling Patent to incorporate features disclosed by either the Abramowitz Patent or the Edwards Patent because earlobe piercings are caused by different kinds of bacteria from mouth piercings and are treated substantially differently. In this case, **the Examiner has established no legitimate reason to combine either Abramowitz and/or Edwards with Kapling because (i) conventional medical wisdom would counsel against retaining mouth jewelry in an infected mouth piercing, and (ii) there is no evidence that the small amount of any anti-septic substance that the structures disclosed by Abramowitz and/or**

Edwards could dispense would be clinically effective in treating and/or preventing any infection of a piercing of the mouth.

In other words, different parts of the body are prone to substantially different types of infections that are also managed differently using substantially different medical therapies. The articles discussed above demonstrate these facts as does the Ashton Declaration. The Examiner has adduced no facts whatsoever to show that medical therapies for treating earlobe piercing infections are suitable for treating infections of a mouth piercing. On the other hand, Applicant has demonstrated by the articles discussed above, and by the Ashton Declaration, that medical therapies for treating an earlobe piercing infection are not suitable for treating an infection of a mouth piercing. **The Examiner has adduced no facts to rebut these medical facts demonstrated by Applicant**.

The Examiner concedes that treatment of infected mouth piercings is different from treatment of infected earring piercings (Office Action, dated November 26, 2008, at 20, lines 8-13). The Examiner gives "Official Notice" that

> "there is a wide selection of the appropriate medications for use in the mouth that is commonly used to treat infections and a person of ordinary skill in the art will use select these medication when treating the mouth."
> (Office Action, dated November 26, 2008, at 20, lines 13-15)

I respectfully traversed the Examiner's "Official Notice" on page 28, lines 9-12, of Amendment (I), of record, on the grounds that there is no topical medication suitable for treating infected mouth piercings such as may be dispensed by the hypothetical device resulting from the combination of the Kapling Patent, the Abramowitz Patent, the Edwards Patents, and the Lefkowitz Patent. **As evident from the Perkins Article (of record), an infected tongue stud should be removed**. The Ashton Declaration, at 19, line 1, to 20, line 4, further demonstrates that using a tongue stud with a means for dispensing a substance would be medically contraindicated for treating an infected tongue piercing, and that the amount of topical medication that could be dispensed from the Examiner's hypothetical device would be in homeopathic doses so that it would have no practical efficacy at treating or preventing an infected mouth piercing.

The Examiner is reminded that the Administrative Procedure Act requires Examiner's rejections employ "reasoned decision making" based on evidence from a fully developed administrative record. In re Lee, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002). Patentability determinations that are based on what the Examiner believes is "basic knowledge" and "common sense," and that otherwise lacks substantial evidentiary support, are impermissible. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed.Cir. 2001). In this case, Applicant has adduced substantial evidence to rebut the Examiner's unsubstantiated contention that there is a legitimate reason to combine the disclosures of the Kapling Patent, the Abramowitz Patent, the Edwards Patents, and the Lefkowitz Patent for the purposes of preventing and/or treating infected tongue piercings. Therefore, the Examiner's alleged reason is no more than an unsubstantiated "Official Notice."

In view of the evidence of record rebutting the Examiner's argument regarding motivation to combine disclosures, **the Examiner must now substantiate the "Official Notice" by providing substantial evidence, such as a valid prior art reference, to show that there is, in fact, a wide selection of topical medications appropriate for use in the mouth for treating infected mouth piercings**. The Examiner's evidence must also show that a person of ordinary skill in the art would have had a reasonable expectation of success at treating infected mouth piercings in the dosages that could be dispensed by the Examiner's hypothetical tongue and mouth stud having a means for dispensing a substance.

The Lefkowitz Patent also fails to provide a legitimate reason to justify the combination of Kapling with either Abramowitz and/or Edwards because the device disclosed by Lefkowitz dispenses a breath deodorizing solution that may contain a medication for deodorizing breath (Lefkowitz Patent, col. 2, lines 64-68). The Lefkowitz Patent does not teach, or suggest, a device for dispensing medication for treating an infected piercing of the mouth, and the Lefkowitz Patent does not teach, or suggest, that a bar bell stud could be used to dispense a breath deodorizer or related breath deodorizing medication.

For all of the above reasons, the Examiner has failed to establish a prima facie case of

obviousness against the invention recited by independent claims 21, 31, 36 and 37.

ix. No Reasonable Expectation of Success Even if the Combinations Proposed by the Examiner Were Made

A proper rejection under Section 103 requires showing (1) that a person of ordinary skill in the art would have had a legitimate reason to attempt to make the composition or device, or to carry out the claimed process, and (2) that the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). In this case, assuming that the Examiner has established a legitimate reason to justify the combination of the Kapling Patent with the Abramowitz Patent and/or the Edwards Patent (which is an invalid assumption), the Examiner has still failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of success of arriving at the claimed invention if the combination were made.

Claims 36 and 37 recite

> "the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member."

If a hypothetical device were made according to the Examiner by combining the features disclosed by Abramowitz or Edwards with the bar bell stud of Kapling, the result would be **inoperative** if the tube (14) or (30) were made "solid...without an internal cavity" (i.e., not hollow). As shown by Figure 10 of Abramowitz, and by Figure 2 of Edwards, it is necessary for the tube to be hollow in order for medicament to be ejected from the reservoirs (44) and (16), respectively. Otherwise, the hypothetical device proposed by the Examiner would be inoperative because, if the tube is made solid and not hollow, then the medicament remains trapped in the reservoir.

The Federal Circuit has ruled that a combination of prior art that would be inoperative actually teaches away from the combination and cannot establish a prima facie case of obviousness.

McGinley v. Franklin Sports Inc., 60 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 2001). Therefore, the Examiner has failed to establish a prima facie case of obviousness against claims 36 and 37 because any combination of Kapling with either Abramowitz and/or Edwards with the tube made "solid...without an internal cavity" instead of hollow would be inoperative.

With respect to claims 21, 31, 36, and 37, the Examiner has failed to show a reasonable expectation of success that the combination of Kapling with Abramowitz and/or Edwards would operate to dispense the substance "into the wearer's mouth...by dissolving the substance over time in the wearer's saliva." On the contrary, the Examiner explicitly admits that the proposed combination does not teach operation in such a manner (Office Action, dated November 26, 2008, at 5, lines 5-8, and at 12, lines 11-14; Office Action, dated March 24, 2008, at 6, lines 5-7, and at 11, lines 8-9). Instead, the Examiner speculates that perhaps the device could operate in such a manner. Applicant contends that such speculation as to the operation of the hypothetical construct resulting from the Examiner's combination of Kapling, Abramowitz, Edwards, and Lefkowitz falls short of a "reasonable expectation of success." Furthermore, Applicant has demonstrated, as discussed above, that the Examiner's hypothetical construct is not likely to operate in the manner claimed by independent claims 21, 31, 36, and 37. Therefore, the Examiner has failed to establish a prima facie case of obviousness against claims 21, 31, 36 and 37 because the Examiner has failed to demonstrate that the combination of Kapling with either Abramowitz and/or Edwards would result in a device that dispenses a substance (e.g., a medicament) into the mouth of a wearer by dissolving the substance in the wearer's saliva.

The combination of Kapling with Abramowitz and/or Edwards would operate to dispense the substance by injection (i.e., solely or at least in part) and not "into the wearer's mouth **solely** by dissolving the substance over time in the wearer's saliva" as recited by claims 21, 31, 36 and 37. Therefore, a person of ordinary skill in the art would have not enjoyed a reasonable expectation of success of arriving at the invention recited by claims 21, 31, 36 and 37 even if the combination of disclosures proposed by the Examiner was made.

In addition to failing to demonstrate a reasonable expectation of success, the Examiner has failed, for all of the above reasons, to demonstrate that the combination of Kapling, Abramowitz, Edwards, and Lefkowitz is enabling. The Federal Circuit has held that the combination of the prior art must be enabled. In re Kumar, 418 F.3d 1361, 1369 (Fed. Cir. 2005). Therefore, the Examiner has additionally failed to establish a prima facie case of obviousness because the Examiner has failed to establish that the combination of Kapling, Abramowitz, Edwards and Lefkowitz is enabled.

III. CONCLUSION

Claims 38, 39, 42-45, 48 and 49 have been allowed.

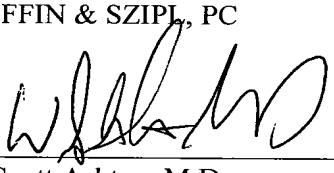
With respect to independent claims 21, 31, 36 and 37, the Examiner has failed to establish a prima facie case of obviousness against these claims because the combination of the Kapling Patent, the Black Patent, the Abramowitz Patent, the Lefkowitz Patent, and the Edwards Patent, (i) fails to teach each and every limitation of the claims as admitted by the Examiner, and (ii) the Examiner has failed to establish any legitimate reason to justify these combinations. Furthermore, (iii) the Examiner has failed to establish that the combination of the Kapling Patent, the Abramowitz Patent, the Lefkowitz Patent, and the Edwards Patent would be enabling and/or that by making the combination a person of ordinary skill in the art would have a reasonable expectation of arriving at the claimed invention. Also, the Examiner's obviousness rejections are based on an improper retrospective view of inherency, such as is prohibited by In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989), and the Examiner relies on multiple unsubstantiated "Official Notices" that the Examiner has not, and cannot, substantiate with evidence.

For all of the above reasons, claims 21-27, 31, 36-39 and 42-49 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed Applicant.

Respectfully submitted,

GRIFFIN & SZIPL, PC



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